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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,712	08/18/1999	JOHN SEFTON	17224(AP)	4667

7590

12/03/2003

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/367,712

Applicant(s)

SEFTON, JOHN

Examiner

Barbara P. Badio, Ph.D.

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-8,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-8,10 and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. The rejection of claims 5, 12 and 13 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is made moot by the cancellation of the instant claims.

3. The rejection of claims 1-3, 6-8, 10 and 11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained.

Applicant argues that notwithstanding any prima facie obviousness that the Examiner and the Board may believe exists, that the specification of the present application now contains evidence of unexpected results, which are sufficient to overcome the obviousness rejection. Accordingly, applicant argues that it is clear from Example 1 and Figure 2 that the combination of tazarotene and a high potency corticosteroid is surprisingly more efficacious than the other combinations tested. Applicant's argument was considered but not persuasive for the following reasons.

Example 1 and the Figures compare alternative topical application of 0.1% tazarotene gel and a placebo, 1% hydrocortisone acetate (low-potency corticosteroid), 0.05% alcometasone dipropionate (medium-potency corticosteroid) or 0.1%

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betamethasone valerate (high-potency corticosteroid). However, in order to argue unexpected and/or unobvious results, the amount of corticosteroid in each case has to be kept constant. As shown above, applicant's argument of unexpected results utilizing tazarotene and betamethasone valerate versus alcometasone dipropionate is based on a higher concentration of betamethasone valerate than that of alcometasone dipropionate. The skilled artisan would have the reasonable expectation that the higher concentration of betamethasone valerate would result in better improvement over treatment with lower concentration of alcometasone dipropionate. In addition, the skilled artisan would have the reasonable expectation that a higher potency corticosteroid would provide a better improvement over treatment with medium- or low-potency corticosteroids and, thus, applicant's argument would not be unexpected or unobvious to the skilled artisan.

For these reasons and those given in previous Office Actions, the rejection of claims 1-3, 6-8, 10 and 11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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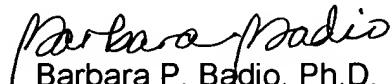
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 6:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
December 2, 2003